| PUBLIC HEALTH, SERVICE APPLICATION FOR A VARIAN PUBLIC HEALTH SERVICE FROM 21 CER 1040 11 (c) FO   |   |  | Form Approved No. 57R0068                      |
|--|---|--|--|
| FOOD AND DRUG ADMINISTRATION   | FROM 21 CFR 1040.11 (c) FOR A   |  |  |
| )  | LASER LIGHT SHOW, DISPLAY OR DEVICE   |  | DOCKET NUMBER                                  |
| JTE: No laser light show or display device may vary from compliance with 21 CFR 1040.11(c) in design   |   |  |  |
| or use without the approval of th  | is application in accorda   | nce with 21 CFR 1010.4.  |  |
| INSTRUCTIONS  1. Check all applicable boxes and type or print to 2. Submit an original and four (4) copies   | the requested information   | n. 3. Mail your application Administratio Roo. 4. Enter Docket Num   | m 4-65, 5600 Fishers Lane, Rockville, MD 20857 |
| 1. NAME OF COMPANY   |   |  |  |
| L R P HOSPITALITY DBA PAMPA  | LANES   |  |  |
| 2. ADDRESS OF COMPANY (Include ZIP Code)   |   |  |  |
| 31925 Van Dyke Warren, MI.   | 48093   |  |  |
| 3. NAME OF RESPONSIBLE PERSON  | 4. TELEPHONE NO. (Include area code)  |  | 5. DATE OF SUBMISSION                          |
| Jeff Bruzzese  | 810-264-8877  |  | 8/12/99  |
| 6. The applicant requests the variance to be in effect a variance for only two years. If a longer period   | ffect for a period of <u>2</u> years from the date of issu d is requested a justification must be attached as |  | . (In general the Agency will approve          |
|  | DUCT DESCRIPTI  |  |  |
| a. LIST NAME AND MODEL NUMBER(S)   |   |  |  |
| MOBOLAZER ML10-200, ML10-300,  | ML10-300W, ML10   | -1000  |  |
| b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED  A LASER DISPLAY DEVICE  A PROJECTOR FOR A LASER LIGHT SHOW  X A LASER LIGHT SHOW  OTHER (Specify)  PROJECTORS ARE INTENDED FOR SALE, LEASE OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS  d. PRODUCT IS INTENDED FOR USE IN A  PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE  THEATER  DISCOTHEQUE OR NIGHT CLUB  PAVILION  INDOOR ARENA  OUTDOOR ARENA  MUSEUM  OUTDOOR ENCLOSED AREA  X OTHER (Specify)  BOWLING Center  E. PRODUCT IS INTENDED TO BE USED  X AT ONLY ONE (fixed) LOCATION  AT A VARIETY OF (tour) LOCATIONS  OTHER (Specify) |   | f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION  MORE THAN 15 DAYS  MORE THAN 5 BUT NOT MORE THAN 15 DAYS  LESS THAN 5 DAYS  g. TOUR IS INTENDED TO RUN FOR  MORE THAN 6 MONTHS  1-6 MONTHS  LESS THAN 1 MONTH  OTHER (Specify)  h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS  FRONT SCREEN PROJECTIONS  REAR SCREEN PROJECTIONS  HOLOGRAPHIC DISPLAYS  MULTIPLE REFLECTIONS (multiple channels or diffraction effects)  AUDIENCE SCANNING  REFLECTIONS FROM STATIONARY MIRROR(S) OR  MIRRORED SURFACES  STATIONARY IRRADIATION OF ROTATING MIRROR BALL(S)  OR OTHER MIRRORED SHAPES  SCANNING IRRADIATION OF ROTATING MIRROR BALL(S)  FIBER OPTIC PROJECTIONS  FOG, SMOKE OR OTHER SCATTERING EFFECTS  OTHER (Specify) |  |
| 8.   |   | 2  |  |
| LASER MEDIUM(Ar, He-Ne, etc.)  | WAVELENGT   | DIATION LEVELS HS (nm)   | PEAK POWER (Watts)                             |
| Argon 🚉  | 455-514 nm  | <del></del>  | 2 Watts  |
| Argon / Krypton  | 455-670 nm  |  | 500 mW   |
| 9. IF ANY LASER RADIATION IS PULSED OR SCAN AMPLITUDE Scanned: D.C. to 500 Hz Am   | NED, GIVE THE PULSE (<br>plitude: 60 deg., pe   |  | L<br>ID SCANNING FREQUENCY AND                 |
| REASON FOR REQUESTING VARIANCE  X COMPLIANCE WITH THE LIMITS OF 21 CFF COMPLIANCE WOULD LIMIT THE OUTPUT SUFFICIENTLY VISIBLE OTHER OR ADDITIONAL EXPLANATION (SA  | POWER TO THE EXTENT   | TRICT THE INTENDED US<br>THAT THE DESIRED EFF  | SE OF THE PRODUCT BECAUSE<br>ECTS WOULD NOT BE |

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VARI

- JANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE AFFECTABLE STANDARD

  X IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11 (c) IN THAT THE ACCESSIBLE EMISSION LEVEL WOULD EXCEED THE ACCESSIBLE EMISSION LIMITS OF CLASS I OR CLASS II
  - IT IS PROPOSED TO DEVIATE FROM THE PROVISION OF 21 CFR 1040.11 (c) AS FOLLOWS:

ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

- X LASER LIGHT SHOWS AND DISPLAYS ARE ACCEPTED POPULAR MEDIA IN ENTERTAINMENT AND THE ARTS, USE OF POWER LEVELS IN EXCESS OF THE LIMITS IMPOSED BY 21 CFR 1040.11 (c) IS NECESSARY TO ACHIEVE THE REQUIRED EFFECTS IN THESE MEDIA.
- OTHER OR ADDITIONAL ADVANTAGES (describe and explain)
- EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. (Check as many boxes as apply. In item 14 "Remarks", justify any boxes not checked, using additional sheets as necessary. State any other means of radiation protection that will be used.)
- X ALL LASER PRODUCTS, SYSTEMS AND PROJECTORS WILL BE CERTIFIED TO COMPLY WITH 21 CFR 1040.10 AND THE CONDITIONS OF THIS VARIANCE AND WILL BE REPORTED AS REQUIRED BY 24 CFR 1002.10 AND 1002.12 USING THE REPORTING GUIDES PROVIDED FOR SUCH PURPOSE. THESE ACTIONS WILL BE ACCOMPLISHED PRIOR TO ANY INTRODUCTION INTO COMMERCE.
- X EFFECTS NOT SPECIFICALLY INDICATED IN THIS VARIANCE APPLICATION WILL NOT BE PERFORMED, NO OTHER EFFECTS WILL BE ADDED UNTIL AN AMENDMENT TO THE VARIANCE HAS BEEN OBTAINED AND THE REQUIRED REPORTS OR SUPPLEMENTS, AS APPLICABLE, HAVE BEEN SUBMITTED.
- X SCANNING, PROJECTION, OR REFLECTION OF LASER AND COLLATERAL RADIATION (LIGHT SHOW RADIATION) INTO AUDIENCE OR
  OTHER ACCESSIBLE UNCONTROLLED AREAS WILL NOT BE PERMITTED EXCEPT FOR DIFFUSE REFLECTIONS PRODUCED BY THE
  ATMOSPHERE, ADDED ATMOSPHERIC SCATTERING MEDIA, AND TARGET SCREENS.
- X LASER RADIATION LEVELS IN EXCESS OF THE LIMITS OF CLASS I WILL NOT BE PERMITTED AT ANY POINT LESS THAN 3.0 METERS ABOVE ANY SURFACE UPON WHICH PERSONS OTHER THAN OPERATORS, PERFORMERS, OR EMPLOYEES ARE PERMITTED TO OR 2.5 METERS BELOW OR IN LATERAL SEPARATION FROM ANY PLACE WHERE SUCH PERSONS ARE PERMITTED TO BE. OPERATORS, PERFORMERS, AND EMPLOYEES WILL NOT BE REQUIRED OR ALLOWED TO VIEW RADIATION ABOVE THE LIMITS OF CLASS I OR BE EXPOSED TO RADIATION ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11 (c).
- ANY PRODUCT WHICH RELIES ON SCANNING TO MEET ACCESS, EXPOSURE, OR PRODUCT CLASS LIMITS WILL INCORPORATE A SCANNING SAFEGUARD SYSTEM WHICH DIRECTLY SENSES SCANNER MOTION AND WHICH WILL REACT FAST ENOUGH TO PRECLUDE EXCEEDING THE APPLICABLE LIMIT.
- X ALL LASER LIGHT SHOWS SHALL BE UNDER THE DIRECT AN PERSONAL CONTROL OF TRAINED, COMPETENT OPERATOR(S). THE OPERATOR(S) WILL:
  - (1) IMMEDIATELY TERMINATE THE EMISSION OF LIGHT SHOW RADIATION IN THE EVENT OF ANY UNSAFE CONDITION;
  - (2) BE LOCATED WHERE ALL BEAM PATHS CAN BE DIRECTLY OBSERVED AT ALL TIMES; AND
  - (3) BE AN EMPLOYEE OF THE VARIANCE HOLDER WHO WILL BE RESPONSIBLE FOR THE TRAINING AND CONDUCT OF OPERATOR
- . X THE MAXIMUM LASER PROJECTOR OUTPUT POWER WILL NOT EXCEED THE LEVEL REQUIRED TO OBTAIN THE INTENDED EFFECTS.
- X THE PROJECTION SYSTEM (I.E., THE PROJECTOR AND ALL OTHER COMPONENTS USED TO PRODUCE THE LIGHTING EFFECTS WILL BE SECURELY MOUNTED OR IMMOBILIZED TO PREVENT UNINTENDED MOVEMENT OR MISALIGNMENT. BEAM LIMITS WILL BE PROVIDED AS AN INHERENT PART OF THE SYSTEM DESIGN TO PREVENT OVERFILLING OF SCREENS, BEAM STOPS, TARGETS, FTC.
- X LASER PROJECTORS WILL NOT BE DELIVERED TO ANY OTHER PARTY UNDER AN AGREEMENT OF SALE, LEASE, OR LOAN UNLESS AND UNTIL THE RECIPIENT DEMONSTRATES THAT THEY HAVE A VARIANCE IN EFFECT AT THE TIME OF DELIVERY THAT PERMITS THEM TO PRODUCE LASER LIGHT SHOWS INCORPORATING SUCH PROJECTOR.
- X IN ADDITION TO THE REQUIREMENTS OF 21 CFR 1040.10 (h), THE MANUFACTURER OF LASER PROJECTORS/SYSTEMS WILL PROVIDE TO PARTIES WHO PURCHASE, LEASE, OR BORROW THE EQUIPMENT, ADEQUATE USER'S INSTRUCTIONS FOR SAFE INSTALLATION AND OPERATION AND WHICH EXPLAIN THE RESPONSIBILITY OF THE RECIPIENT AS AN INDEPENDENT LIGHT SHOW MANUFACTURER TO SUBMIT THE REQUIRED REPORTS AND APPLY FOR AND OBTAIN A VARIANCE FROM CDRH PRIOR TO INTRODUCTION INTO COMMERCE OF ANY LASER LIGHT SHOWS.
- X THE REQUIREMENTS OF 21 CFR 1002.30 (a)(1) AND (2) WILL BE ACCOMPLISHED THROUGH THE USE OF WRITTEN PROCEDURES
  FOR SETUP ALIGNMENT, TESTING, AND PERFORMANCE OF EACH SHOW. THESE PROCEDURES WILL BE IN SUFFICIENT DETAIL TO
  ENSURE COMPLIANCE WITH 21 CFR 1040.10. THE CONDITIONS OF THIS VARIANCE, AND CONTROL OF ACCESS TO RADIATION
  AREAS USING THE PROCEDURES DESCRIBED IN THE ANSI Z136.1 STANDARD FOR THE SAFE USE OF LASERS (AMERICAN NATIONAL
  STANDARDS INSTITUTE, 1430 BROADWAY, NEW YORK, NY 10018) OR ANY OTHER EQUIVALENT USER CONSENSUS STANDARD AND
  AND, WHERE APPLICABLE, STATE OR LOCAL REQUIREMENTS. LASER RADIATION AREAS WHICH CAN CONTAIN RADIATION LEVELS
  ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c), WILL BE CLEARLY IDENTIFIED BY THE POSTING OF WARNING SIGNS AND/OR
  RESTRICTED ACCESS THROUGH PHYSICAL MEANS (SUCH AS PRESSURE SWITCHES, PHOTOCELLS, BARRIERS, GUARDS, ETC.).
  THESE REQUIREMENTS APPLY TO TEMPORARY AREAS (SUCH AS DURING SETUP AND ALIGNMENT PROCEDURES) AND TO FINAL
  OR PERMANENT AREAS. THE VARIANCE HOLDER WILL RETAIN THE RECORDS OF THESE PROCEDURES AND THE RESULTS OF ALL
  TESTS AS REQUIRED BY 21 CFR 1002.31, A COPY OF THE VARIANCE APPLICATION, THE APPROVAL LETTER, CURRENT PROCEDURES
  AND RECORDS RELATING TO EACH PARTICULAR SHOW WILL BE WITH THE OPERATOR OR OTHER RESPONSIBLE INDIVIDUAL AND
  WILL BE MADE AVAILABLE FOR INSPECTION BY FDA AND OTHER RESPONSIBLE AUTHORITIES

- ( ) ADVANCED WRITTEN NOTIFICATION WILL BE MADE AS EARLY AS POSSIBLE TO APPROPRIATE FEDERAL, STATE AND LOCAL AUTHORITIES PROVIDING SHOW ITINERARY WITH DATES AND LOCATIONS CLEARLY AND COMPLETELY IDENTIFIED AND A BASIC DESCRIPTION OF PROPOSED EFFECTS INCLUDING A STATEMENT OF THE MAXIMUM POWER OUTPUT INTENDED. SUCH NOTIFICATION WILL BE MADE, BUT NOT NECESSARILY LIMITED TO:
  - (1) THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF COMPLIANCE (HFZ-312), 2098 GAITHER ROAD, ROCKVILLE, MD 20880. PROVIDING THE INITIAL AND CLOSING DATES FOR THE FIXED INSTALLATION AND THE ITINERARY FOR MOBILE SHOWS IN ADDITION, UNLESS ALL ASPECTS OF EACH SHOW HAVE BEEN REPORTED AND THE ACCESSION NUMBERS CLEARLY REFERENCED. EACH NOTICE WILL INCLUDE DETAILED DESCRIPTIONS OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE PERFORMED IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE REGULATIONS AND THIS VARIANCE.
  - (2) THE FEDERAL AVIATION ADMINISTRATION (FAA) FOR ANY PROJECTIONS INTO OPEN AIRSPACE AT ANY TIME (I.E., INCLUDING SET-UP, ALIGNMENT, REHEARSALS PERFORMANCES, ETC.). IF THE FAA OBJECT TO ANY LASER EFFECTS, THE OBJECTIONS WILL BE RESOLVED AND ANY CONDITIONS REQUESTED BY THE FAA WILL BE ADHERED TO.

    IF THESE CONDITIONS CANNOT BE MET, THE OBJECTIONABLE CONDITIONS WILL BE DELETED FROM THE SHOW
  - (3) STATE AND LOCAL RADIATION CONTROL OFFICES/AGENCIES FOR ALL SHOWS TO BE PERFORMED WITHIN THEIR JURISDICTIONS. ALL REQUIREMENTS OF STATE AND LOCAL LAW WILL BE SATISFIED AND ANY OBJECTIONS RAISED BY LOCAL AUTHORITIES WILL BE RESOLVED OR THE EFFECTS DELETED. (LISTS OF FEDERAL AND STATE OFFICES ARE AVAILABLE FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH UPON REQUEST.)

## 14. REMARKS

## CERTIFICATION

I CERTIFY that all the above information and statements are true, complete and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance application may be revoked if this application is found to be false, misleading or incorrect in any material way. I have submitted/will submit all reports required by 21 CFR 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director Bureau of Radiological Health to supply such other information that may be necessary to evaluate and act on this application.

15. SIGNATURE

16. NAME (print or type)
Jeff Bruzzese

17. TITLE

General Manager